DETAILED ACTION

Receipt is acknowledged of Applicant's Request for Continued Examination, Amendment, and Declaration filed on 03/19/2012.

- Claims 53, 61, 68, and 76-77 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/19/2012 has been entered.

Declaration under 37 CFR 1.132

The Declaration under 37 CFR 1.132 filed 03/19/2012 is insufficient to overcome the rejections as set forth in the last Office action as discussed below in the *Response to Argument* section.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent

and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 53, 61, 76, and 77 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over copending Application No. 10/598,315; 10/598,306; 10/598,355; 11/441,455; 11/735,268; 11/561,968; 11/569,343; 11/859,249;12/297,017; 12/305,747. Although the conflicting claims are

not identical, they are not patentably distinct from each other because the copending application recites a compressed, layered pharmaceutical tablet formed in a tablet die having an embossed bottom tablet punch and a top tablet punch, said tablet comprising one or more layers of a powder or granulation composition containing an effective amount of one or more active drugs, wherein said active drug-containing composition is filled into the tablet die wherein the embossed bottom tablet punch forms a divided active bottom layer or layers, said bottom layer or layers being tamped using the top tablet punch to provide first and second unitary segments each having a level top surface following said tamping; and one or more layers of a second powder or granulation composition containing either an undetectable amount of drug or a pharmacologically ineffective amount of drug, wherein said second composition is filled onto the level top surface of said first and second unitary segments in the tablet die, said second composition forming an undivided, non-unitary inactive top segment having a bottom and top surface, wherein only the bottom surface contacts said level top surfaces of said first and second unitary active segments, wherein the bottom active unitary segments and top inactive non-unitary segment are compressed to form a whole tablet, said tablet being divisible by breaking through the inactive non-unitary segment, without breaking of the first and second unitary segments, wherein the terms "bottom" and "top" refer to the orientation of the tablet in the tablet die during compression (see 10/598,315 at claim 1). Note, the other co-applications disclosed using an embossed lower/bottom punch.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 53, 61, 76 and 77 are rejected under 35 U.S.C. 102(b) as being anticipate by HESS et al (CH 648754; translation provided by USPTO).

Applicant's claims are directed to a composition comprising of: a first bottom segment containing a drug and a score greater than 50% through the maximum height of said first bottom segment; and a second unscored top segment substantially free of drug and contacting said first segment, wherein breaking through second segment without substantial consequent breakage of the first segment. Additional limitations include: controlled release, such as sustained-release; covered with an inert inactive composition.

HESS teaches a composition comprised of: a first segment containing a drug and a score greater than 50% through the maximum height of said first segment (see Figure 1a, wherein the drug is in S1; and page 8, under Figure 1 – page 9); and a second unscored segment contacting said first layer is a placebo (see Figure 1a, wherein placebo layer is S2; and page 8 under Fig 1 – page 9), which reads on substantially free

of drug. Additional limitations include: when the tablet is divided, the layer S1 remains without broken parts (see pg. 8, last paragraph), which would read on "wherein breaking through second segment without substantial consequent breakage of the first segment"; controlled release, such as slow release (see abstract), which reads on sustained-release; covered with an inert inactive composition, such as soluble film coating (see pg. 7, 1st full paragraph), which would also read on capsule.

Note, the top and bottom orientation can be reversed by turning the Figures upside down.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 53, 61, 68, 76-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over HESS et al (CH 648754; translation provided by USPTO) in view of MEDRI (US 4,789,546) and SASMAL et al (US 2005/0026992).

As discussed above, HESS teaches a composition comprised of: a first segment containing a drug and a score greater than 50% through the maximum height of said first segment (see Figure 1a, wherein the drug is in S1; and page 8, under Figure 1 – page 9); and a second unscored segment contacting said first layer is a placebo (see Figure 1a, wherein placebo layer is S2; and page 8 under Fig 1 – page 9), which reads

on substantially free of drug. Additional limitations include: when the tablet is divided, the layer S1 remains without broken parts (see pg. 8, last paragraph), which would read on "wherein breaking through second segment without substantial consequent breakage of the first segment"; controlled release, such as slow release (see abstract), which reads on sustained-release; covered with an inert inactive composition, such as soluble film coating (see pg. 7, 1st full paragraph), which would also read on capsule. Note, the top and bottom orientation can be reversed by turning the Figures upside down.

MEDRI teaches the prior art had known of using different colorants, such as colored dyes (see col. 1, line 31), in different layers of a multiple-layer tablet to enable a patient to identify the tablet (see abstract).

SASMAL teaches a capsule composition comprised of minitablets that can be film coated (see [0043]; and [0053])), wherein the composition promotes patient compliance by avoiding inconvenience of taking multiple doses of medicines (see (0006]).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a colorant for visually distinguishing said layer from another layer. The person of ordinary skill in the art would have been motivated to make those modifications, because it would enable a patient to identify the tablet, and reasonably would have expected success because the references are in the same field of endeavor, such as pharmaceutical drugs.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate using a capsule to put the tablets in. The person of ordinary skill in the art would have been motivated to make those modifications, because it would promote patient compliance by avoiding inconvenience of taking multiple doses of medicines, and reasonably would have expected success because the references are in the same field of endeavor, such as pharmaceutical drugs.

Response to Arguments

Applicant argues that Hess does not teach a dosage form wherein the top layer (S1) is inactive (placebo) and further does not describe a tablet wherein the top layer S1 is inactive and the bottom layer (S2) is active, as claimed. Moreover, Hess describes (and shows in Figures 1-3) that only the top layer - not the bottom layer - is scored when a score is formed in only one layer. The only instance that a score is formed on the bottom layer is when a score is formed in both the top and bottom layers. This is not the claimed invention, which has a bottom scored segment and a top unscored segment. It is emphasized that the current claims expressly recite that the score is formed in the "bottom" segment and that the top segment is unscored.

The Examiner finds this argument unpersuasive, because as discussed above, the top and bottom orientation can be reversed by turning the Figures upside down. Wherein the active S1 would be the bottom layer and the placebo S2 would be the top layer.

Applicant argues that a scored bottom layer, as claimed, must be formed using an embossed bottom punch and a top punch that is not embossed (resulting in a top segment that is unscored, as claimed).

The Examiner finds this argument unpersuasive, because even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this instance, the prior art's product has the same design and limitations as claimed by Applicant.

Applicant argues that the Declaration filed on 03/19/2012 allows a "tamping step", which provides a more complete separation of the layer forming the active segment or segments.

The Examiner finds this unpersuasive, because Applicant's claims do not recite a "tamping step".

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618